

REMARKS

Applicants submit this response to the Examiner's Notice of Non-compliant Amendment of October 16, 2008. Applicant's previous response on June 23, 2008 to the Examiner's previous Notice of Non-compliant Amendment of May 22, 2008 was rejected because it allegedly did not provide a written record which distinctly and specifically point out the supposed errors in the Office Action. Accordingly, Applicants have incorporated their arguments from their original response dated April 11, 2008 into this response.

Claim 54 was corrected to reinsert the word "and" that was inadvertently omitted in Applicants' response of April 11, 2008. Applicants also amended claim 54 to recite specific collagen deficient conditions as suggested by the Examiner during the May 9, 2008 interview. Claims 68 and 69 contain the same amendments that were submitted with the Applicants' previous response on April 11, 2008.

Finally, new claims 70 and 71 were added to recite further specific collagen deficient conditions. Support for claim 70 can be found throughout the specification and specifically at pages 26 to 28. Support for claim 71 can be found throughout the specification and specifically at pages 33 to 35.

1. Status of Application

Upon entry of the attached response, claims 54-71 will be pending.

- Claims 54-56, 58, 59, 61-64 and 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 6,071,526 to Schmidt *et al.*
- Claims 54-69 are rejected under 35 U.S.C. §102(b) as being anticipated by publication WO 97/36570 to Schmidt *et al.*

2. Interview

Applicants thank the Examiner for meeting with their representatives on May 9, 2008. The instant response to the Notice of Non-compliant Amendment, including the current amendments were discussed.

3. Discussion

In addition to the response below, the Examiner is referred to Applicants' previously filed response of April 11, 2008 as well as the May 9, 2008 interview with the Applicants' representatives.

I. The Rejection of Claims 54-56, 58, 59, 61-64 and 67 Under The Doctrine Of Obviousness-Type Double Patenting

The Examiner maintained the rejection of claims 54-56, 58, 59, 61-64 and 67 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 6,071,526 ('526 patent) to Schmidt *et al.* Applicants respectfully traverse this rejection.

Applicants respectfully maintain that the '526 patent does not teach or suggest identifying a patient having a collagen deficient condition. The Examiner argues that "an identifying step can be an entirely mental step. In instances wherein the step of 'of identifying a subject suffering from a collagen deficient condition' is entirely a mental step, the claimed processes are entirely indistinguishable from the '526 patent method because all of the outwardly visible steps in the claimed process are the same steps as carried out by the '526 patent." Office Action at 2. The Examiner has attempted to diminish the "identifying" limitation by incorrectly characterizing it as *de minimis* and inherently a "mental step." Applicants respectfully maintain that this step is an outwardly visible and active step that requires the identification of a subject suffering a certain condition and treatment of that identified subject. For example, collagen deficient conditions of the outer skin can include slackness of the outer skin or the formation of wrinkles and stretched striae. Specification at 22-23, Examples 1-4. Striae can be characterized by a decrease in collagen content (Specification at 21) and decreased collagen in skin can be assessed by sonography (Specification at 22). In marked contrast, cellulite can be diagnosed by identifying, among others, pallor, lower temperature, and decreased elasticity after compression or muscular contraction; roughness of the skin, i.e. "orange peel skin syndrome;" or granulations in the deep levels of the skin which can be detected by palpitation. Thus, the required "identifying" limitation is more than a mental step because it requires, for example, actual physical evaluation of the subject. In order to clarify this point, Applicants have amended claim 54 to recite the "administering a pharmaceutical composition comprising an aromatase inhibitor to said subject" that was previously identified.

The '526 patent does not teach or suggest the step of "identifying a patient having a collagen deficient condition, selected from the group consisting of wrinkles, striae, atony of the skin, or sun exposure to the skin" as recited in claim 54. The '526 patent is directed to treating disordered

connective fatty tissue of the inner skin, in particular, cellulite. See Abstract. In fact, the '526 patent does not provide any teaching or motivation that the topical administering of a pharmaceutical composition comprising an aromatase inhibitor would be effective in treating a subject suffering from a collagen deficient condition enumerated in the claims. See Specification, page 23, lines 21-29. Furthermore, the treatment of a disordered connective fatty tissue of the inner skin, such as cellulite, does not necessarily implicate the treatment of a collagen deficient condition. For example, the specification discloses that a collagen deficient condition can include atony or slackness of the outer skin or the formation of wrinkles and stretched striae. Specification, page 22-23. Moreover, the Examiner does not acknowledge that the '526 patent does not disclose, teach or suggest the stabilization, increase, or restoration of collagen resulting from the inhibition of the production of estrogen – a surprising and unexpected result disclosed by the Applicants. See Specification, page 23. Accordingly, for the reasons stated above, Applicants respectfully request withdrawal of this rejection.

II. The Rejection of Claims 54-69 Under 35 U.S.C. §102(b)

The Examiner maintained the rejection of claims 54-69 under 35 U.S.C. §102(b) as being anticipated by publication WO 97/36570 to Schmidt *et al* ('570 publication). Applicants respectfully traverse this rejection.

U.S. Patent No. 6,071,526 ('526 patent) to Schmidt *et al.* is a divisional of U.S. Patent No. 5,945,109 ('109 patent) to Schmidt *et al.*, which claims priority to German Patent Application No. DE 196 12 748 ('748 German Application). The '570 publication is a German language publication (except for an English abstract) that claims priority, and has a disclosure similar to the '748 German Application. As previously explained in Applicants' May 18, 2005 (and January 20, 2005) Response, the '526 and '109 patents correspond to the '570 publication. (see May 18, 2005 Response at page 6).

As explained previously with respect to the '526 patent, above, the examiner has failed to recognize that the "identifying" step is not merely a "mental step." The step is an outwardly visible and active step that requires the identification of a subject suffering a certain condition and treatment of that identified subject. As discussed above, the "identifying" step of the present invention would involve different characterizations and diagnoses than identifying a person with cellulite. Thus, the required "identifying" limitation is more than a mental step because it requires, for example, actual physical evaluation of the subject. In order to clarify this point, Applicants have amended claims 54 and 68-69 to recite the administering of a pharmaceutical composition comprising an aromatase inhibitor to said subject that was previously identified.

Moreover, claims 68-69 recite "identifying a subject suffering from wrinkles, strias or atony of the skin" and "identifying a subject suffering from sun exposure to the skin," respectively. New claims 70-71 recite "identifying a subject suffering from an injured ligament, tendon, or other collagen containing part of the body" and "identifying a subject in need of controlling hair growth," respectively. Neither the '570 publication nor the '526 patent disclose such steps. Accordingly, Applicants respectfully traverse this rejection and submit that claims 54-69 are neither anticipated nor obvious in view of the cited reference, and the claim is therefore allowable.

4. Conclusion

Applicants believe that this application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections and early notice of allowance to that effect is respectfully requested. Should the Examiner have any questions, comments or suggestions in furtherance of the prosecution of this application, she is invited to contact the applicants' representative by telephone at the number indicated below. If there are any other fees due in connection with the filing of this response, please charge the fees as follows:

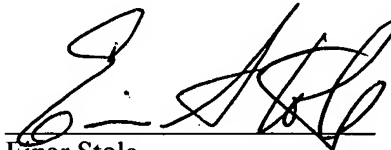
EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 13-3250, reference No. 38891.00100. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F. R. § 1.136(a)(3).

Respectfully submitted,

MILBANK, TWEED, HADLEY & McCLOY LLP

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